

**UNITED STATES APPLICATION**

**FOR**

**GRANT OF LETTERS PATENT**

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**FOR**

**BLOOD PURIFICATION SYSTEM**

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**BLOOD PURIFICATION SYSTEM**Background of the Invention(1) Field of the Invention

The present invention relates generally to a system and method for ultraviolet disinfection and, more particularly, to a system and method for ultraviolet disinfection of blood.

(2) Description of the Prior Art

It is known in the art to use ultraviolet light (UV) for the disinfection treatment of blood. Ultraviolet light, at the germicidal wavelength of 253.7 nanometers, alters the genetic (DNA) material in cells so that bacteria, viruses, molds, algae, and other microorganisms can no longer reproduce. The microorganisms are considered dead, and the risk of disease from them is eliminated. As the air flows past the UV lamps in UV disinfection systems, the microorganisms are exposed to a lethal dose of UV energy. UV dose is measured as the product of UV light intensity times the exposure time within the UV lamp array. Microbiologists have determined the effective dose of UV energy to be approximately about 34,000 microwatt- seconds/cm<sup>2</sup> needed to destroy pathogens as well as indicator organisms found in wastewater. Typical prior art disinfection systems and devices emit UV light at approximately 254 nm, which penetrates the outer cell membrane of microorganisms, passes through the cell body, reaches the DNA and alters the genetic material of the microorganism, destroying it without chemicals by rendering it unable to reproduce.

Ultraviolet light is classified into three wavelength ranges: UV-C, from about 200 nanometers (nm) to about 280 nm; UV-B, from about 280 nm to about 315 nm; and UV-

1 A, from about 315 nm to about 400 nm. Generally, UV light, and in particular, UV-C  
2 light is "germicidal," i.e., it deactivates the DNA of bacteria, viruses and other pathogens  
3 and thus destroys their ability to multiply and cause disease, effectively resulting in  
4 sterilization of the microorganisms. Specifically, UV "C" light causes damage to the  
5 nucleic acid of microorganisms by forming covalent bonds between certain adjacent  
6 bases in the DNA. The formation of these bonds prevents the DNA from being read  
7 correctly, and the organism is neither able to produce molecules essential for life process,  
8 nor is it able to reproduce. In fact, when an organism is unable to produce these essential  
9 molecules or is unable to replicate, it dies. UV light with a wavelength of approximately  
10 between about 250 to about 260 nm provides the highest germicidal effectiveness. While  
11 susceptibility to UV light varies, exposure to UV energy for about 20 to about 34  
12 milliwatt-seconds/cm<sup>2</sup> is adequate to deactivate approximately 99 percent of the  
13 pathogens.

14 Bacterial contamination of blood is a deadly problem that can frequently result in  
15 the death of the recipient. 182 deaths from blood transfusions were reported to the U.S.  
16 Food and Drug Administration from 1986 to 1991. 16 percent of these deaths were  
17 linked to bacterial contamination. There are lab tests to screen donated blood for HIV,  
18 hepatitis and other viruses, but none that look for bacteria. Therefore, it is unknown how  
19 many of the 20 million pints of blood and blood products used in transfusions each year  
20 are contaminated with bacteria. Blood can become contaminated even if the donor is not  
21 septicemic. For example, the needle used to siphon blood from a donor can pick up  
22 bacteria from the skin. A core of skin is caught inside the needle as the needle is pushed  
23 through the skin. The pressure of the blood then pushes the core into the bag.

1           The most common bacteria found so far are ones, which can grow in cold  
2   temperatures, and thus can grow in blood and blood products stored in refrigerators. A  
3   more serious problem is contamination of platelets. Once separated from the blood,  
4   platelets must be stored at room temperature, which is a good environment for bacteria to  
5   grow.

6           Thus, a blood sterilization process is needed that can sterilize blood in a rapid,  
7   effective, and inexpensive manner.

#### 8   Summary of the Invention

9           The present invention is directed to a UV purification system and method for  
10   treating blood.

11           One object of the present invention is to provide a UV disinfection system for  
12   treating blood configured and arranged to function effectively with at least one UV light  
13   source or lamp.

14           Another object of the present invention is to provide a UV-ready blood purifier  
15   that is designed to accept a UV light source input for the purpose of sterilization of  
16   microorganisms.

17           Another object of the present invention includes presentation of the UV light  
18   source detached from and remotely connectable with the blood purifier via fiber optic,  
19   UV transmission lines.

20           Accordingly, one aspect of the present invention is to provide a UV disinfection  
21   system for treating blood configured and arranged to function effectively with at least one  
22   UV light source or lamp.

1 Another aspect of the present invention is to provide a UV-ready blood purifier  
2 that is designed to accept a UV light source input for the purpose of sterilization of  
3 microorganisms.

4 Another aspect of the present invention is to provide presentation of the UV light  
5 source detached from and remotely connectable with the blood purifier via fiber optic,  
6 UV transmission lines, and including the use of optical components.

7 These and other aspects of the present invention will become apparent to those  
8 skilled in the art after a reading of the following description of the preferred embodiment  
9 according to the present invention when considered with the drawings.

#### 10 Brief Description of the Drawings

11 Figure 1 is a schematic diagram of the complete UV blood disinfection system.

12 Figure 2 is a representation of a vertical riser configuration (VRC).

#### 13 Detailed Description of the Preferred Embodiments

14 In the following description, like reference characters designate like or  
15 corresponding parts throughout the several views. Also in the following description, it is  
16 to be understood that such terms as "forward," "rearward," "front," "back," "right,"  
17 "left," "upwardly," "downwardly," and the like are words of convenience and are not to  
18 be construed as limiting terms.

19 Referring now to the drawings in general, the illustrations are for the purpose of  
20 describing a preferred embodiment of the invention and are not intended to limit the  
21 invention thereto. Figure 1 shows a schematic diagram of a UV blood disinfection  
22 system, generally described as 10. In the preferred embodiment, a power supply 12  
23 powers a UV light source 14. The UV light source is composed of a UV lamp 15, source

1 optical components 16, and a housing 17. UV light generated by the UV lamp contained  
2 within the housing is focused and controlled by the means of the source optical  
3 components into at least one UV transmission line 18 that connects to the blood purifier  
4 20 at a portal 22, which may alternatively be at least one portal if more than one light  
5 input is desired, thus transmitting UV light to the blood. The blood purifier portal is  
6 equipped with optical components, or portal optics, 32 that further control the UV light at  
7 the blood purifier 20 in order to provide additional focus and/or control of the UV light  
8 for the disinfection of the blood 24. The blood purifier is composed of a dose zone 34  
9 and a housing 36. The dose zone can include a dose delivery device. The dose zone and  
10 the housing may be equipped with UV reflective optical components, or interior optics  
11 26, and may also be composed of a UV reflective interior surface and/or coating 28. For  
12 longevity as well as UV reflectivity, the interior surfaces may be made of a UV reflective  
13 material selected from the group consisting of UV reflective metals, e.g., stainless steel,  
14 aluminum, or the like. In the preferred embodiment, the blood purifier is made to be  
15 disposable for single-use applications. Additionally, the contribution of the reflectance of  
16 internal surfaces to the efficacy of the system can be capitalized upon by incorporating  
17 UV reflective materials and reflection enhancing two- and three-dimensional design into  
18 the blood purifier. Moreover, additional surfaces to enhance reflectance may be added to  
19 the purifier zone. More particularly, the blood purifier and other components form an  
20 integrated 2- and 3-dimensional design that incorporates UV-reflectant materials, design,  
21 and surfaces that advantageously enhance the efficacy of the system.

22 While generally regarding the UV light source and configuration according to the  
23 present invention, the preferred embodiment includes a UV light source that is remotely

1 connectable to the blood purifier via at least one fiber optic transmission line.  
2 Additionally, the preferred embodiment of the present invention includes at least one  
3 optical component positioned between the UV light source and the UV light source  
4 system output point. Advantageously, the use of optical components enables the system  
5 to maximize the intensity, focus, and control of the UV light rays at the output for any  
6 given UV light source or lamp. Also, optical components, including but not limited to  
7 reflectors, shutters, lenses, splitters, mirrors, rigid and flexible light guides, homogenizer  
8 or mixing rods, manifolds and other couplers, filters, color wheels, and the like, can be  
9 utilized in combination to achieve the desired control and output. Additionally, optical  
10 component such as gratings, dichroic filters, focalizers, gradient lenses, gradient  
11 reflectors, off-axis lenses, and off-axis reflectors may be used. All UV transmissive  
12 optical components included in the present invention are made of UV-transmissive  
13 material and all UV-reflective optical components included in the present invention are  
14 made of UV-reflective material. The fiber optic lines may include quartz fibers, side-  
15 emitting fibers, glass fibers, acrylic fibers, liquid core fibers, hollow-core fibers, core  
16 sheath fibers, dielectric coaxial fibers, or a combination of fibers.

17 With regard to lenses, several embodiments are considered to be within the scope  
18 of the present invention. Imaging lenses, such as a parabolic lens, and non-imaging  
19 lenses, such as gradient lenses, may be used to focus and control light output. More  
20 particularly, a gradient lens collects light through a collecting opening and focuses it to  
21 an area smaller than the area of the collecting opening. This concentration is  
22 accomplished by changing the index of refraction of the lens along the axis of light  
23 transmission in a continuous or semi-continuous fashion, such that the light is “funneled”

1 to the focus area by refraction. An example of gradient lens technology is the Gradium®  
2 Lens manufactured by Solaria Corporation. Alternatively, a toroidal reflector, as  
3 described in United States Patent 5,836,667, is used. In this embodiment, a UV radiation  
4 source, such as an arc lamp, is located at a point displaced from the optical axis of a  
5 concave toroidal reflecting surface. The concave primary reflector focuses the radiation  
6 from the source at an off-axis image point that is displaced from the optical axis. The use  
7 of a toroidal reflecting surface enhances the collection efficiency into a small target, such  
8 as an optical fiber, relative to a spherical reflecting surface by substantially reducing  
9 aberrations caused by the off-axis geometry. A second concave reflector is placed  
10 opposite to the first reflector to enhance further the total flux collected by a small target.

11 Additionally, more than one reflector may be used with a lamp. For example,  
12 dual reflectors or three or more reflectors, as taught in US Patents 5,706,376 and  
13 5,862,277, may be incorporated into the preferred embodiment.

14 Notably, any number of lamps including low pressure, medium pressure, high  
15 pressure, and ultra high-pressure lamps, which are made of various materials, e.g., most  
16 commonly mercury (Hg) can be used with the system configuration according to the  
17 present invention, depending upon the blood or influent characteristics and flow rates  
18 through the system. Furthermore, while high and ultra high pressure lamps have not been  
19 used commercially to date by any prior art system, predominantly because of the low  
20 energy efficiency associated with them and the lack of capacity for prior art design and  
21 configuration formulas to include high pressure UV lamps, the present invention is  
22 advantageously suited to accommodate medium to high to ultra high pressure lamps, all



1 of which can be metal, halogen, and a combination metal halide. Additionally, spectral  
2 calibration lamps, electrodeless lamps, and the like can be used.

3 In particular, by way of example and not of limitation, one preferred embodiment  
4 according to the present invention employs a light pump housing a pencil-type spectral  
5 calibration lamp. With a light pump, the number of lamps necessary to treat a given  
6 number of the blood purifiers can be reduced. Also, the lamps are not susceptible to  
7 fouling, since they are not exposed to the blood to be purified. Furthermore, the  
8 maintenance and servicing of the purifier is greatly simplified. The pencil-type spectral  
9 calibration lamps are compact and offer narrow, intense emissions, an average intensity  
10 that is constant and reproducible, and a longer life relative to other high wattage lamps.  
11 Hg (Ar) lamps of this type are generally insensitive to temperature and require only a  
12 two-minute warm-up for the mercury vapor to dominate the discharge, then 30 minutes  
13 for complete stabilization. A Hg(Ar) UV lamp, which is presently commercially  
14 available and supplied by ORIEL Instruments, is used in the preferred embodiment  
15 according to the present invention. The ORIEL Hg(Ar) lamp, model 6035, emits UV  
16 radiation at 254 nm. When operated at 15 mA using a DC power supply, this lamp emits  
17 74 microwatt/cm<sup>2</sup> of 254 nm radiation at 25 cm from the source.

18 Another preferred embodiment according to the present invention employs  
19 medium to high-pressure UV lamps, more preferably high-pressure UV lamps. These  
20 lamps may include mercury and/or mercury halide lamps, such as Hg(Ar), Hg(Xe), and  
21 Hg(Ne).

1 The light generated by these sources is focused via optics and fibers that are  
2 joined by UV-transmissive optical couplers. By way of example and not of limitation,  
3 these couplers can be quartz, liquid-filled, hollow, or dielectric coaxial couplers.

4 The present invention advantageously includes all of the above features, in  
5 particular because the UV lamps are separated from the blood purifier and include a light  
6 delivery system that incorporates optical components. Without the use of optical  
7 components in combination with the UV light source, the intensity of the light could not  
8 be effectively focused, directed, and controlled to provide an efficacious disinfection  
9 because the UV dosage entering the blood purifier would not be great enough to sterilize  
10 the microorganisms. By using optical components incorporated into the blood purifier  
11 itself, the blood purifier need be coupled to only one fiber optic transmission line for the  
12 supply of UV light. Alternately, the fiber optic transmission line and blood purifier may  
13 be simply juxtaposed to allow irradiated of the blood purifier by the light exiting the  
14 transmission line or other optics.

15 The light pump arrangement beneficially extends the lamp life thereby providing  
16 a longer replacement time or lamp life cycle. Since turning the lamp off and on degrades  
17 the lamp life, the system can be constructed and configured such that other appliances  
18 and areas are sterilized intermittently with the blood purifier by simply routing the UV  
19 light to the device or area to be irradiated. Thus, the lamp need not be turned on and off  
20 frequently. However, a timer or other means of system activation can be incorporated  
21 into the blood purifier to control exposure.

22 The UV light source may be presented in at least two primary configurations: a  
23 vertical riser configuration and a planar or horizontal configuration. In the vertical riser

1 configuration the UV light source is positioned above the fluid to be treated and  
2 projecting a UV dose zone downward toward and into the fluid to be treated, with the  
3 fluid moving upward toward the UV light source. Alternatively, the UV light source may  
4 be presented in a planar or horizontal design, wherein the UV light source is positioned  
5 above the fluid to be treated and projecting a UV dose zone downward toward and into  
6 the fluid to be treated, with the fluid moving in a direction substantially perpendicular to  
7 the UV dose zone.

8 The UV light source may be presented in a vertical riser configuration according  
9 to a preferred embodiment of the present invention, as shown generally at 100 in Figure  
10 2, wherein the fluid enters into the vertical riser configuration (VRC) via a pipe or outlet  
11 120 and passes therethrough prior to discharge from the pipe or outlet 140 for  
12 consumption or end use. Furthermore, the VRC includes at least one UV light source  
13 130. This UV light source 130 is part of a lamp assembly, as shown generally at 150 in  
14 Figure 2. The lamp assembly 150 is composed of a housing 160 that encases the UV  
15 light source 130, at least one optical component 180, and UV light ray output (not shown)  
16 that exits the housing. The UV light ray output exits the housing above the fluid 210 to  
17 be treated, this fluid entering the VRC through the inlet pipe 120 and being forced  
18 upward through the interior pipe 220 of the VRC 100 toward the UV light ray output that  
19 is projected downward toward the fluid surface and into the fluid 210 to be treated, once  
20 again with the fluid moving upward toward the UV light source 130. At least one  
21 interface plate 240 may be fitted to the top of the interior pipe 220, thus increasing the  
22 exposure time of the fluid 210 to the UV light ray output. The at least one interface plate  
23 240 contains a hole or holes 250 that allows fluid rising upward through the interior pipe

1 220 to exit at the top of the pipe. The fluid then traverses across the superior surface 260  
2 of the interface plate 240 to the plate edge 270, where it then descends into the exterior  
3 chamber 280 of the VRC. The fluid is prevented from returning into the interior pipe 220  
4 by a base plate 290 that solidly connects the exterior of the interior pipe 220 with the  
5 interior of the outer pipe 295. The fluid then exits the VRC 100 through the pipe or  
6 outlet 140. The UV light rays may be projected downward from a UV light source or a  
7 lamp system that includes optical components. These optical components may include,  
8 but are not limited to, reflectors, shutters, lenses, splitters, focalizers, mirrors, rigid and  
9 flexible light guides, homogenizer or mixing rods, manifolds and other couplers, filters,  
10 gratings, diffractors, color wheels, and the like. These optical components are internal to  
11 the lamp system and are positioned between the UV light source or lamp and the UV ray  
12 light output of the lamp assembly, thereby focusing, directing, and controlling the light  
13 ray output that irradiates the fluid and that sterilizes any microorganisms that exist in the  
14 fluid. The UV light ray output irradiates and may also be transmitted through the fluid.  
15 UV light ray output that is transmitted through the fluid and strikes the reflective interior  
16 surfaces (not shown) of the VRC components is reflected back into the fluid where it may  
17 strike microorganism. The reflection of the UV light ray output back into the fluid by the  
18 reflective interior surfaces of the VRC components enhances the killing capacity of the  
19 VRC system.

20 Several UV dose zones are established within the VRC system. The first zone is  
21 the air UV dose zone which occurs just beneath the UV light source and just above the  
22 blood and the at least one interface plate. The next zone is the interface plate UV dose  
23 zone which occurs at the intersection of the water and the at least one interface plate. The

1 at least one interface plate is used to provide a surface zone for UV disinfection above the  
2 fluid and to provide additional treatment means for balancing pH, affecting effluent  
3 chemistry, providing a catalyst, and the like. The last zone is the submerged UV dose  
4 zone, which creates a variable UV dose zone that decreases in effectiveness at greater  
5 distances from the UV light source.

6 Alternatively to the vertical configuration, the UV light source may be presented  
7 in a planar or horizontal design, as shown generally at 300 in Figure 1, wherein at least  
8 one UV transmission line 18 that connects to the blood purifier 20 at a portal 22, which  
9 may alternatively be at least one portal if more than one light input is desired. The blood  
10 purifier portal is equipped with optical components, or portal optics, 32 that further  
11 control the UV light at the blood purifier 20 in order to provide additional focus and/or  
12 control of the UV light for the disinfection of the blood 24. The portal optics project the  
13 UV light, creating a UV dose zone, onto the blood which is flowing past in a  
14 perpendicular manner from the influent point 37 in a direction substantially perpendicular  
15 to the UV light source toward the effluent point 38. The dose zone and the housing may  
16 be equipped with UV reflective optical components, or interior optics 26, and may also  
17 be composed of a UV reflective interior surface and/or coating 28. For longevity as well  
18 as UV reflectivity, the interior surfaces may be made of a UV reflective material selected  
19 from the group consisting of UV reflective metals, e.g., stainless steel, aluminum, or the  
20 like. In the preferred embodiment, the blood purifier is made to be disposable for single-  
21 use applications. Additionally, the contribution of the reflectance of internal surfaces to  
22 the efficacy of the system can be capitalized upon by incorporating UV reflective  
23 materials and reflection enhancing two- and three-dimensional design into the blood

1 purifier. Moreover, additional surfaces to enhance reflectance may be added to the  
2 purifier zone. More particularly, the blood purifier and other components form an  
3 integrated 2- and 3-dimensional design that incorporates UV-reflectant materials, design,  
4 and surfaces that advantageously enhance the efficacy of the system.

5 Several UV dose zones are established within the system. The first zone is the air  
6 UV dose zone, which occurs just beneath the UV light source and just above the blood.  
7 The next zone is the air/blood interface UV dose zone, which occurs at the air and blood  
8 interface. The last zone is the submerged UV dose zone, which occurs within the flowing  
9 blood.

10 A key factor in the design of a UV disinfection system and method according to  
11 the present invention involves the integration of two main components, including the  
12 non-submerged UV light source system and the hydraulic system. The hydraulic system  
13 includes a hydraulic tube and pumping system for forcing the fluid through the tube  
14 toward the light source(s). The present invention includes the use of hydraulic systems  
15 that comprise a transporter or pumping system, and at least one interface plate. The  
16 hydraulic system serves at least three functions: it carries blood to the UV dose region,  
17 regulates the flow to the UV dose region, and discharges the treated blood to a container.

18 Such an embodiment is easily scalable. For example, the size of the embodiment  
19 may extend from a small, portable application with a single point of UV irradiation to a  
20 large, multipoint application.

21 In the preferred embodiment, at least one portal optic is positioned at the portal  
22 opening of the blood purifier, between the portal opening and the blood purifier. The  
23 function of the at least one portal optic is to control the distribution of UV light in the

1 blood purifier in order to enhance the UV disinfecting and degrading capacity of the  
2 system. The portal optics may be similar to those described for the source optics,  
3 including but not limited to reflectors, shutters, lenses, splitters, mirrors, rigid and  
4 flexible light guides, homogenizer or mixing rods, manifolds and other couplers, filters,  
5 color wheels, and the like, can be utilized in combination to achieve the desired control  
6 and output, as set forth in U.S. patent numbers 6,027,237; 5,917,986; 5,911,020;  
7 5,892,867; 5,862,277; 5,857,041; 5,832,151; 5,790,725; 5,790,723; 5,751,870; 5,708,737;  
8 5,706,376; 5,682,448; 5,661,828; 5,559,911; D417,920 and co-pending applications  
9 09/523,609; 09/587,678; 09/630,245; 09/723,679; 09/723,731; 09/724,068; 09/724,180;  
10 and 09/723,733, which are commonly owned by the assignee of the present invention.  
11 Additionally, optical component such as gratings, dichroic filters, focalizers, gradient  
12 lenses, and off-axis reflectors may be used. Finally, side-emitting fiber optic  
13 transmission lines may be used to distribute the UV light over the filter.

14 All UV transmissive optical components for the portal optics are made of UV-  
15 transmissive material and all UV-reflective optical components for the portal optics are  
16 made of UV-reflective material. These optics may extend into the blood purifier. For  
17 example, fiber optic transmission lines may be incorporated into the blood purifier and  
18 used to route UV light to the various areas of the blood purifier. The fiber optic lines  
19 may include quartz fibers, side-emitting fibers, glass fibers, acrylic fibers, liquid core  
20 fibers, hollow-core fibers, core sheath fibers, dielectric coaxial fibers, or a combination of  
21 fibers. The optics may also be incorporated into the structure of the blood purifier. For  
22 example, the interior of the blood purifier may be of a UV reflective material such that  
23 UV radiation striking these surfaces is reflected back through the blood.

1           Such a system of UV disinfection can be easily integrated into the blood  
2   purification function cycle by activating the UV light source or allowing irradiation of the  
3   blood purifier interior at a predetermined time in the blood purification function cycle.  
4   Alternately, the UV disinfection system may be manually activated when desired or may  
5   be programmed to activate when blood is detected.

6           Such a device has several advantages. First, the disinfected blood is completely  
7   free from microorganisms without requiring the addition of chemicals or other additives  
8   that would increase the chemical residue in the blood. Next, the use of removeably  
9   connectable portal optics to separate the light source from the fluid container allows for  
10   continuous use of the light source without the need for disinfection of the light source  
11   after the disinfection of every container of fluid. This extends the lamp life significantly.  
12   Also, the system can be used to disinfect blood as it is being collected, as the dose  
13   delivery device can be inserted in the blood collection line prior to the collection  
14   container and UV light routed to the dose delivery device with fiber optic transmission  
15   lines. By disinfecting blood at collection, the loss of blood due to bacterial contamination  
16   at collection can be prevented. In fact, because the primary contamination of blood is  
17   from the core of skin pushed into the needle at insertion, the intensity of light during the  
18   first few seconds of blood collection can be greatly increased to sterilize the core of skin  
19   before it has a chance to contaminate all the blood. Moreover, use of a light pump in  
20   such an application will allow for the collection of blood from multiple persons or  
21   animals simultaneously. Such an arrangement would eliminate the need for a lamp or  
22   light source at every point of application. Because it may not be necessary to  
23   continuously irradiate each point of application, such an arrangement would allow the



1 same size lamp as would be require for a single application to service multiple  
2 applications intermittently and/or on demand, thus utilizing the lamp more efficiently.  
3 Additionally, placing the lamp exterior to the application reduces the risk of glass and/or  
4 mercury contaminating the blood should the lamp or lamp housing break.

5 Certain modifications and improvements will occur to those skilled in the art upon  
6 a reading of the foregoing description. By way of example, various optical components  
7 are used depending upon the particular UV light source or lamp selection for a given  
8 system. Moreover, a wide range of applications are contemplated within the scope of the  
9 present invention, including application of the UV blood purification system and method  
10 to purifiers involved in the manufacture of biological products and the like.

11 All modifications and improvements have been deleted herein for the sake of  
12 conciseness and readability but are properly within the scope of the following claims.  
13